As of November 7

■Pipeline of prescription pharmaceuticals (Clinical Stage)

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
diquafosol sodium	DE-089	Dry eye	Merck Sharp & Dohme Corp. (U.S.)	China					Sep-2018	
A dry eye treatment which stimulates secretion of mucin and aqueous components from the corneal and conjunctival epithelium. Its mechanism of action is different from existing treatments. Launched in December 2010 in Japan. Launched in October 2013 in Korea. Launched in February 2016 in Vietnam. Launched in April 2016 in Thailand. Currently seeking sequential approvals for marketing in Asia. Launched in September 2018 in China.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
sirolimus	DE-109	Uveitis	Original	U.S.						
				Japan						
				Europe						
				Asia				Apr-2015		
An intravitreal injection with immunosuppressive effect, anti-angiogenic effect, etc. Planning to start an additional clinical trial in November 2018 in the U.S. NDA filed in April 2015 in Asia.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
epinastine hydrochloride	DE-114A	Allergic conjunctivitis	Nippon Boehringer Ingelheim	Japan				Sep-2018		
An H_1 receptor antagonist with membrane-stabilizing function, as treatment for allergic conjunctivitis. High dose drug. Filed for manufacturing and marketing approval in September 2018 and planning to receive approval in July ~ December 2019 in Japan.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
omidenepag isopropyl	DE-117	Glaucoma/ Ocular hypertension	Co-development with Ube Industries	U.S.						
				Japan					Sep-2018	
				Asia						
An EP2 receptor agonist with a new mechanism of action. Started Phase 3 in September 2018 and planning to complete in January ~ June 2020 in the U.S. Received manufacturing and marketing approval in September 2018 in Japan. Plan to be listed on NHI price list and launch soon after. Started Phase 3 in December 2016 and planning to complete in the 2nd half of FY2018 in Asia.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
carotuximab	DE-122	Wet Age-related macular degeneration	TRACON Pharmaceuticals	U.S.		(Phase 2a)				
An intravitreal injection of anti-endoglin antibody. Started Phase 2a in July 2017 and planning to complete in January ~ June 2019 for development in the U.S.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
sepetaprost	DE-126	Glaucoma/ Ocular hypertension	ONO PHARMACEUTICAL	U.S.		(Phase 2b)				
				Japan		(Phase 2b)				
A prostaglandin analogue eye drop drug product with a novel mode of action that is both FP and EP3 receptors dual agonist for the treatment of glaucoma and ocular hypertension. Started Phase 2b in July 2017 in the U.S. and Japan.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
atropine sulfate	DE-127	Myopia	Singapore Health Services, Nanyang Technological University	Asia						
Muscarinic antagonist which reduces juvenile myopia progression. Started Phase 2 in November 2017 and planning to complete in the 2nd half of FY2019 in Asia.										

—	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
—	DE-128 *(MicroShunt)*	Glaucoma	Original	U.S.			(Phase 2/3)			
				Europe						
In August 2016, acquired InnFocus, developer of MicroShunt. MicroShunt is a drainage implant device designed to lower and sustain intraocular pressure (IOP) for the treatment of primary open-angle glaucoma through the drainage of aqueous humor. Conducting Phase 2/3 in the U.S. and Europe in advance of application to FDA and planning to complete 2018~2019. Planning U.S. launch in 2020 ~ 2021. Received CE Mark in Europe.										

Generic name	Dev. name	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
ciclosporin	DE-076B (Cyclokat)	Severe keratitis in patients with dry eye	Original	U.S.						
				Asia						Dec-2017
An ophthalmic emulsion to treat severe keratitis in adult patients with dry eye through an immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue absorption. Launched in July 2015 in Germany and U.K. with successive launches following in European countries. Launched in December 2017 in Thailand and Korea with successive launches following in Asian countries.										

Generic name	Dev. name	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
ciclosporin	DE-076C (Vekacia)	Vernal keratoconjunctivitis	Original	Europe						Oct-2018
An ophthalmic emulsion which improves vernal keratoconjunctivitis by immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue absorption. Received the Marketing Authorization Application approval from the European Commission Agency in July 2018 and launched in October 2018 in U.K.										

Generic name	Dev. name	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
latanoprost	DE-130A (Catioprost)	Glaucoma/ Ocular hypertension	Original	Europe						
An ophthalmic emulsion of a prostaglandin F2α derivative, for the treatment of glaucoma and ocular hypertension.										

■Changes from Q1 FY18 (August 1, 2018)

Dev. code / name	Changes
DE-089	Launched in September 2018 in China.
DE-114A	Filed for manufacturing and marketing approval in September 2018 in Japan.
DE-117	Started Phase 3 in September 2018 in the U.S. Received manufacturing and marketing approval in September 2018 in Japan.
DE-076C (Vekacia)	Launched in October 2018 in U.K.